EXHIBIT

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EXAMINER
PIHONAK, SARAH

ART UNIT	PAPER NUMBER
1627	

NOTIFICATION DATE	DELIVERY MODE
08/22/2022	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 17/841,567	Applicant(s) WOOLLAM, Grahame	
	Examiner SARAH PIHONAK	Art Unit 1627	AIA (FITF) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 6/15/22.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 21-41 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 21-41 is/are rejected.

8) ☑ Claim(s) 21 is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 6/15/22 is/are: a)☑ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

weNotice of Pre-AIA or AIA Status

The present application is being examined under the pre-AIA first to invent provisions.

Priority

This application, filed on 6/15/22, is a CON of 17301280, filed on 4/15/21. 16715225 is a continuation of 16130079, filed 09/13/2018; 16130079 is a continuation of 15677264, filed 08/15/2017; 15677264 is a continuation of 15206877, filed 07/11/2016; 15206877 is a continuation of 14955515, filed 12/01/2015; 14955515 is a continuation of 14547455, filed 11/19/2014; 14547455 is a continuation of 13973174, filed 08/22/2013; 13973174 is a division of 12835964, filed 07/14/2010; 12835964 Claims Priority from Provisional Application 61225803, filed 07/15/2009.

Status of Claims

1. Claims 21-41 are currently pending. Claims 1-20 have been canceled. A track one status has been granted.

2. Claims 21-41 were examined and are rejected.

Claim Rejections-Statutory Double Patenting

3. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process... may obtain a patent therefor..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v.*

Eagle Mfg. Co., 151 U.S. 186 (1894); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the claims that are directed to the same invention so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 21-27 and 32-41 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 30-36, 44-47, and 51-56 of copending Application No. 17301280 (reference application). This is a provisional statutory double patenting rejection since the claims directed to the same invention have not in fact been patented.

Claim Rejections-Nonstatutory Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed.

Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP § 2146 *et seq.* for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 21-41 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-4 and 8 of U.S. Patent No. 8541451 B2 in view of Axt et. al., WO 2006099165 A1 (publ. 9/21/2006, cited in an IDS). The instant claims are drawn to a process of preparing a pharmaceutical composition comprising a crystalline freebase of biphenyl-2-

ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1-ylmethyl)benzoyl]methylamino}-ethyl)piperidin-4-yl ester, and a pharmaceutical composition comprising a crystalline freebase of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1-ylmethyl)benzoyl]methylamino}-ethyl)piperidin-4-yl ester dissolved in a solvent, comprising diffraction peaks at 2θ values of 6.6±0.1, 13.1±0.1, 18.6±0.1, 19.7±0.1, and 20.2±0.1; having a melting point of about 125˚C. The claims of US '451 are the same crystalline compound as recited in the instantly claimed composition, having the same powder x-ray diffraction peaks (see claims 1-2 of US '451 and instant claims 32-35), and a pharmaceutical composition comprising the compound in a carrier. The instant claims also recite an aqueous, isotonic carrier, wherein the composition has a pH between 4-6 along with a citrate buffer, and about 0.05 µg/mL-10 mg/mL compound in the composition, limitations that are not recited by the claims of US '451. However, Axt teaches crystalline forms of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1-ylmethyl)benzoyl]methylamino}-ethyl)piperidin-4-yl ester freebase in pharmaceutical compositions for treating pulmonary disorders (title & abstract; p. 1, lines 5-10). Axt additionally teaches an aqueous isotonic solution as a carrier for the compound, wherein the solution has a pH between 4-6 and a citrate buffer (p. 3, lines 3-9), wherein the amount of compound in solution is from about 0.05 µg/mL-10 mg/mL (p. 16, lines 25-27). Therefore, it would have been prima facie obvious to have incorporated an aqueous, isotonic carrier, citrate buffer, and concentration range of crystalline freebase compound into the composition claimed in US '451, having a pH range between 4-6, because Axt teaches this carrier, buffer, and pH range for the same compound. The instant claims and claims of US '451 are therefore not patentably distinct because both sets of claims encompass the same crystalline form of

biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1-ylmethyl)benzoyl]methylamino}-ethyl)piperidin-4-yl ester freebase, and the composition of the instant claims and the claims of US '451 are obvious variants of each other.

5. Claims 21-41 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-10 and 13-17 of U.S. Patent No. 9226896 B2 in view of Axt et. al., WO 2006099165 A1 (publ. 9/21/2006, cited in an IDS). The instant claims are drawn to a process of preparing a pharmaceutical composition comprising a crystalline freebase of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1-ylmethyl)benzoyl]methylamino}-ethyl)piperidin-4-yl ester, and a pharmaceutical composition comprising a crystalline freebase of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1-ylmethyl)benzoyl]methylamino}-ethyl)piperidin-4-yl ester dissolved in a solvent, comprising diffraction peaks at 2θ values of 6.6±0.1, 13.1±0.1, 18.6±0.1, 19.7±0.1, and 20.2±0.1; having a melting point of about 125˚C. The claims of US '896 are drawn to a pharmaceutical composition comprising a crystalline freebase of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1-ylmethyl)benzoyl]methylamino}-ethyl)piperidin-4-yl ester having the same powder x-ray diffraction peaks as recited in the instant claims, and a pharmaceutically acceptable propellant (see claims 1-2 of US '896, and instant claims 32-35). The claims of US '896 further recite the inclusion of a beta-2 adrenergic receptor agonist, a steroidal agent, a phosphodiesterase-4 inhibitor, and 1,1,1,2-tetrafluoroethane, or 1,1,1,2,3,3,3-heptafluoroethane as the propellants; ethanol as a solvent; and a surfactant selected from sorbitan trioleate, oleic acid, lecithin, and glycerin. Although these limitations are not expressly recited in the instant claims, it would have been prima facie

obvious to have incorporated these components into the instantly claimed composition in view of Axt. Axt teaches crystalline forms of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1-ylmethyl)benzoyl]methylamino}-ethyl)piperidin-4-yl ester freebase in pharmaceutical compositions for treating pulmonary disorders (title & abstract; p. 1, lines 5-10). Axt teaches the compositions to further comprise a beta-2 adrenergic receptor agonist and a steroidal anti-inflammatory agent and/or a phosphodiesterase-4 inhibitor, a pharmaceutical carrier, and a propellant, with 1,1,1,2-tetrafluoroethane, or 1,1,1,2,3,3,3-heptafluoroethane taught as propellants (p. 2, line 25-p. 3, line 2; p. 17, line 31-p. 18, line 14). Axt additionally teaches an aqueous isotonic solution as a carrier for the compound, wherein the solution has a pH between 4-6 (p. 3, lines 3-9); ethanol or pentane as cosolvents; and surfactants such as sorbitan trioleate, oleic acid, lecithin, and glycerin (p. 17, line 31-p. 18, line 14). Since Axt teaches these excipients and solvents to be included in a pharmaceutical composition comprising the same compound as recited by the instant claims, it would have been prima facie obvious to one of ordinary skill in the art to have incorporated these excipients, cosolvents, and propellants into the instantly claimed composition. The instant claims recite an aqueous, isotonic carrier, wherein the composition has a pH between 4-6 along with a citrate buffer, and about 0.05 µg/mL-10 mg/mL compound in the composition, limitations that are not recited by the claims of US '896. However, Axt additionally teaches an aqueous isotonic solution as a carrier for the compound, wherein the solution has a pH between 4-6 and a citrate buffer (p. 3, lines 3-9) wherein the amount of compound in solution is from about 0.05 µg/mL-10 mg/mL (p. 16, lines 25-27). As such, it would have been prima facie obvious to have incorporated such a

carrier into the composition claimed in US '896. The instant claims and the claims of US '896 are therefore not patentably distinct.

6. Claims 21-41 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-3, 5-9, and 11-12 of U.S. Patent No. 9415041 B2 in view of Axt et. al., WO 2006099165 A1 (publ. 9/21/2006, cited in an IDS). The instant claims are drawn to a process of preparing a pharmaceutical composition comprising a crystalline freebase of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1-ylmethyl)benzoyl]methylamino}-ethyl)piperidin-4-yl ester, and a pharmaceutical composition comprising a crystalline freebase of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1-ylmethyl)benzoyl]methylamino}-ethyl)piperidin-4-yl ester dissolved in a solvent, comprising diffraction peaks at 2θ values of 6.6±0.1, 13.1±0.1, 18.6±0.1, 19.7±0.1, and 20.2±0.1; having a melting point of about 125˚C. The claims of US '041 are drawn to a pharmaceutical composition comprising a crystalline freebase of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1-ylmethyl)benzoyl]methylamino}-ethyl)piperidin-4-yl ester having the same powder x-ray diffraction peaks as recited in the instant claims, and a dry powder excipient (see claims 1 & 11 of US '041, and instant claims 32-35). The claims of US '041 further recite the inclusion of a beta-2 adrenergic receptor agonist, a steroidal agent, a phosphodiesterase-4 inhibitor, and lactose as an excipient. Although these limitations are not expressly recited in the instant claims, it would have been prima facie obvious to have incorporated these components into the instantly claimed composition in view of Axt. Axt teaches crystalline forms of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-

carbamoylpiperidin-1-ylmethyl)benzoyl]methylamino}-ethyl)piperidin-4-yl ester freebase in pharmaceutical compositions for treating pulmonary disorders (title & abstract; p. 1, lines 5-10). Axt teaches the compositions to further comprise a beta-2 adrenergic receptor agonist such as formoterol, and a steroidal anti-inflammatory agent and/or a phosphodiesterase-4 inhibitor, a pharmaceutical carrier, and lactose as an excipient (p. 2, line 25-p. 3, line 2; p. 15, line 23-p. 16, line 2). Since Axt teaches these excipients and solvents to be included in a pharmaceutical composition comprising the same compound as recited by the instant claims, it would have been prima facie obvious to one of ordinary skill in the art to have incorporated these excipients into the instantly claimed composition. The instant claims recite an aqueous, isotonic carrier, wherein the composition has a pH between 4-6 along with a citrate buffer, and the amount of compound present in the composition is from about 0.05 µg/mL-10 mg/mL, limitations that are not recited by the claims of US '041. However, Axt additionally teaches an aqueous isotonic solution as a carrier for the compound, wherein the solution has a pH between 4-6 and a citrate buffer (p. 3, lines 3-9), wherein the amount of compound in solution is from about 0.05 µg/mL-10 mg/mL (p. 16, lines 25-27). As such, it would have been prima facie obvious to have incorporated such a carrier, and this concentration range of compound into the composition claimed in US '041. The instant claims and the claims of US '041 are therefore not patentably distinct.

7. Claims 21-41 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 9765028 B2 in view of Axt et. al., WO 2006099165 A1 (publ. 9/21/2006, cited in an IDS). The instant claims are drawn to a process of

preparing a pharmaceutical composition comprising a crystalline freebase of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1-ylmethyl)benzoyl]methylamino}-ethyl)piperidin-4-yl ester, and a pharmaceutical composition comprising a crystalline freebase of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1-ylmethyl)benzoyl]methylamino}-ethyl)piperidin-4-yl ester dissolved in a solvent, comprising diffraction peaks at 2θ values of 6.6±0.1, 13.1±0.1, 18.6±0.1, 19.7±0.1, and 20.2±0.1; having a melting point of about 125˚C. The claims of US '028 are drawn to crystalline freebase form III of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1-ylmethyl)benzoyl]methylamino}-ethyl)piperidin-4-yl ester having the same powder x-ray diffraction peaks as recited by the instant claims (see claims 1-2 of US '028), and a pharmaceutical composition comprising the compound and an acceptable carrier. Both sets of claims therefore require the same crystalline form of the same compound. The instant claims recite an aqueous, isotonic carrier, wherein the composition has a pH between 4-6, along with a citrate buffer, and the amount of compound present in the composition is from about 0.05 µg/mL-10 mg/mL, limitations that are not recited by the claims of US '028. However, Axt teaches crystalline forms of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1-ylmethyl)benzoyl]methylamino}-ethyl)piperidin-4-yl ester freebase in pharmaceutical compositions for treating pulmonary disorders (title & abstract; p. 1, lines 5-10). Axt additionally teaches an aqueous isotonic solution as a carrier for the compound, wherein the solution has a pH between 4-6, along with a citrate buffer (p. 3, lines 3-9), wherein the amount of compound in solution is from about 0.05 µg/mL-10 mg/mL (p. 16, lines 25-27). It would have been prima facie obvious to have incorporated these components as a carrier, and this concentration range of crystalline freebase compound into the composition claimed in US '028,

because Axt teaches this vehicle for the same compound and concentration range. The instant claims and claims of US '028 are as such not patentably distinct.

8. Claims 21-41 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 10100013 B2. The instant claims are drawn to a process of preparing a pharmaceutical composition comprising a crystalline freebase of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1-ylmethyl)benzoyl]methylamino}-ethyl)piperidin-4-yl ester, and a pharmaceutical composition comprising a crystalline freebase of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1-ylmethyl)benzoyl]methylamino}-ethyl)piperidin-4-yl ester dissolved in a solvent, comprising diffraction peaks at 2θ values of 6.6±0.1, 13.1±0.1, 18.6±0.1, 19.7±0.1, and 20.2±0.1; having a melting point of about 125˚C. The instant claims also recite the composition in an aqueous isotonic solution, having a pH between 4-6, and a citrate buffer (see instant claims 37-40), wherein the amount of crystalline compound in the composition is about 0.05 µg/mL-10 mg/mL (instant claim 41). The claims of US '013 are drawn to a method of preparing a composition comprising dissolving crystalline freebase of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1-ylmethyl)benzoyl]methylamino}-ethyl)piperidin-4-yl ester in a solvent to form an aqueous solution, wherein the compound has the same powder x-ray diffraction peaks as recited in the instant claims. Both sets of claims further recite the solution as isotonic (instant claim 38, claim 6 of US '013); has a pH between 4-6 (instant claim 39 & claim 7 of US '013); a citrate buffer (instant claim 40 & claim 8 of US '013); and from about 0.05 µg/mL-10 mg/mL of the crystalline freebase compound in the composition (instant claim 41 & claim 9 of US '013). Both sets of

claims are not patentably distinct, because the process claimed in US '013 results in the same pharmaceutical composition recited in the instant claims.

9. Claims 21-41 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 10550081 B2 in view of Axt et. al., WO 2006099165 A1 (publ. 9/21/2006, cited in an IDS). The instant claims are drawn to a process of preparing a pharmaceutical composition comprising a crystalline freebase of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1-ylmethyl)benzoyl]methylamino}-ethyl)piperidin-4-yl ester, and a process of preparing a pharmaceutical composition, and a pharmaceutical composition comprising a crystalline freebase of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1-ylmethyl)benzoyl]methylamino}-ethyl)piperidin-4-yl ester dissolved in a solvent, comprising diffraction peaks at 2θ values of 6.6±0.1, 13.1±0.1, 18.6±0.1, 19.7±0.1, and 20.2±0.1; having a melting point of about 125˚C. The claims of US '081 are drawn to crystalline freebase form III of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1-ylmethyl)benzoyl]methylamino}-ethyl)piperidin-4-yl ester having a melting point of about 125˚C and a differential scanning calorimetry thermogram as shown in Fig. 4; and a pharmaceutical composition comprising the compound and an acceptable carrier. The compound recited in both sets of claims is the same crystalline form, as evidenced by the same melting point and differential scanning calorimetry thermogram (see instant claims 27 & 35). The instant claims recite an aqueous, isotonic carrier, wherein the composition has a pH between 4-6, along with a citrate buffer, and the amount of compound present in the composition is from about 0.05 µg/mL-10 mg/mL, limitations that are not recited by the claims of US '081. However, Axt

teaches crystalline forms of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1-ylmethyl)benzoyl]methylamino}-ethyl)piperidin-4-yl ester freebase in pharmaceutical compositions for treating pulmonary disorders (title & abstract; p. 1, lines 5-10). Axt additionally teaches an aqueous isotonic solution as a carrier for the compound, wherein the solution has a pH between 4-6, along with a citrate buffer (p. 3, lines 3-9), wherein the amount of compound in solution is from about 0.05 µg/mL-10 mg/mL (p. 16, lines 25-27). It would have been prima facie obvious to have incorporated these components as a carrier into the composition claimed in US '081, because Axt teaches this vehicle for the same compound. The instant claims and claims of US '081 are as such not patentably distinct.

10. Claims 21-41 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 11008289 B2 in view of Axt et. al., WO 2006099165 A1 (publ. 9/21/2006, cited in an IDS). The instant claims are drawn to a process of preparing a pharmaceutical composition comprising a crystalline freebase of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1-ylmethyl)benzoyl]methylamino}-ethyl)piperidin-4-yl ester, and a pharmaceutical composition comprising a crystalline free base of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1-ylmethyl)benzoyl]methylamino}-ethyl)piperidin-4-yl ester dissolved in a solvent, comprising diffraction peaks at 2θ values of 6.6±0.1, 13.1±0.1, 18.6±0.1, 19.7±0.1, and 20.2±0.1; having a melting point of about 125˚C. The claims of US '289 are drawn to a method for treating chronic obstructive pulmonary disease in a human patient comprising preparing a pharmaceutical composition by dissolving a crystalline freebase biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1-

ylmethyl)benzoyl]methylamino}-ethyl)piperidin-4-yl ester in an aqueous pharmaceutical carrier, wherein the compound has the same powder x-ray diffraction peaks as recited by the instant claims (see claims 21 & 32); and administering the composition using a nebulizer. Both sets of claims recite the carrier as being isotonic (claim 6 of US '289 & instant claim 38); a pH between 4-6 (instant claim 39 & claim 7 of US '289); a citrate buffer (instant claim 40 & claim 8 of US '289); and from about 0.05 µg/mL-10 mg/mL of the compound (instant claim 41 & claim 9 of US '289). Although the instant claims don't recite a method of treating COPD by administering the composition in a nebulizer, it would have been prima facie obvious to have done so in view of Axt. Axt teaches crystalline forms of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1-ylmethyl)benzoyl]methylamino}-ethyl)piperidin-4-yl ester freebase in pharmaceutical compositions for treating pulmonary disorders (title & abstract; p. 1, lines 5-10), including COPD, wherein the composition is administered to a patient in need thereof (p. 3, lines 3-9, and lines 13-26). Therefore, the instant claims and claims of US '289 are obvious variations of each other and are not patentably distinct.

11. Claims 21-41 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 8921396 B2 in view of Axt et. al., WO 2006099165 A1 (publ. 9/21/2006, cited in an IDS). The instant claims are drawn to a process of preparing a pharmaceutical composition comprising a crystalline freebase of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1-ylmethyl)benzoyl]methylamino}-ethyl)piperidin-4-yl ester, and a pharmaceutical composition comprising a crystalline freebase

of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1-ylmethyl)benzoyl]methylamino}-ethyl)piperidin-4-yl ester dissolved in a solvent, comprising diffraction peaks at 2θ values of 6.6±0.1, 13.1±0.1, 18.6±0.1, 19.7±0.1, and 20.2±0.1; having a melting point of about 125˚C. The claims of US '396 are drawn to a method of producing bronchodilation, and a method of treating chronic obstructive pulmonary disease (COPD) or asthma comprising administering to a patient by inhalation a crystalline freebase form III of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1-ylmethyl)benzoyl]methylamino}-ethyl)piperidin-4-yl ester having a melting point of about 125˚C and a differential scanning calorimetry thermogram as shown in Fig. 4. The compound recited in both sets of claims is the same crystalline form, as evidenced by the same melting point, powder x-ray diffraction peaks, and differential scanning calorimetry thermogram (see instant claims 27 & 35, and claims 1-2 of US '396). The instant claims recite an aqueous, isotonic carrier, wherein the composition has a pH between 4-6, along with a citrate buffer, and the amount of compound present in the composition is from about 0.05 µg/mL-10 mg/mL, limitations that are not recited by the claims of US '396. However, Axt teaches crystalline forms of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1-ylmethyl)benzoyl]methylamino}-ethyl)piperidin-4-yl ester freebase in pharmaceutical compositions for treating pulmonary disorders such as COPD or asthma (title & abstract; p. 1, lines 5-10; p. 28, lines 4-13). Administration by inhalation is taught by Axt (p. 3, lines 13-26). Axt additionally teaches an aqueous isotonic solution as a carrier for the compound, wherein the solution has a pH between 4-6, along with a citrate buffer (p. 3, lines 3-9), wherein the amount of compound in solution is from about 0.05 µg/mL-10 mg/mL (p. 16, lines 25-27). It would have been prima facie obvious to have incorporated these components as a carrier into the

composition administered as claimed in US '396, because Axt teaches this vehicle for the same compound. While the instant claims don't recite producing bronchodilation or treating COPD, Axt teaches administering by inhalation compositions comprising a crystalline freebase of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1-ylmethyl)benzoyl]methylamino}-ethyl)piperidin-4-yl ester for treating COPD and asthma, therefore, it would have been prima facie obvious to have treated COPD and produced bronchodilation by administering the composition of the instant claims, by inhalation. The instant claims and claims of US '396 are as such not patentably distinct.

12. Claims 28-31 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 30-40 of copending Application No. 17301280 (reference application). The instant claims are drawn to a process of preparing a pharmaceutical composition comprising dissolving a crystalline freebase of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1-ylmethyl)benzoyl]methylamino}-ethyl)piperidin-4-yl ester in a solvent to form a solution, wherein the crystalline freebase compound has powder x-ray diffraction pattern comprising peaks at 2θ values of 6.6±0.1, 13.1±0.1, 18.6±0.1, 19.7±0.1, and 20.2±0.1, while the copending claims are drawn to a process of preparing a composition comprising dissolving the same crystalline form of the same compound in a solvent. Both sets of claims recite the composition as comprising an aqueous carrier (copending claim 32); isotonic (copending claim 37); a pH between 4-6 (copending claim 38); a citrate buffer (copending claim 39), and about 0.05 µg/mL-10 mg/mL of crystalline freebase compound (copending claim 40). The instant and copending claims are therefore not patentably distinct.

This is a provisional nonstatutory double patenting rejection because the patentably indistinct claims have not in fact been patented.

Claim Objection

13. Claim 21 is objected to because of the following informalities: the claim doesn't end with a period. See MPEP 608.01(m). Appropriate correction is required.

Information Disclosure Statements

14. The IDS filed on 6/15/22 have been considered.

Conclusion

15. Claims 21-41 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARAH PIHONAK whose telephone number is (571)270-7710. The examiner can normally be reached Monday-Friday 9:00-5:30 EST.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kortney Klinkel can be reached on 571-270-5239. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SARAH . PIHONAK
Primary Examiner
Art Unit 1627

/SARAH PIHONAK/
Primary Examiner, Art Unit 1627

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/841,567	06/15/2022	Grahame WOOLLAM	71TD-343862-US10	4866

183577 7590 12/28/2022

Sheppard Mullin Richter & Hampton LLP/Theravance
650 Town Center Drive, 10th Floor
Costa Mesa, CA 92626

EXAMINER
PIHONAK, SARAH

ART UNIT	PAPER NUMBER
1627	

NOTIFICATION DATE	DELIVERY MODE
12/28/2022	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

SheppardMullin_Pair@firsttofile.com
patent@theravance.com
svipdocketing@sheppardmullin.com

Office Action Summary	Application No. 17/841,567	Applicant(s) WOOLLAM, Grahame	
	Examiner SARAH PIHONAK	Art Unit 1627	AIA (FITF) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 11/22/22.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 21-41 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☑ Claim(s) 21-31 is/are allowed.

7) ☑ Claim(s) 32,34 and 36 is/are rejected.

8) ☑ Claim(s) 33,35 and 37-41 is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

Notice of Pre-AIA or AIA Status

The present application is being examined under the pre-AIA first to invent provisions.

Status of Claims

1. Claims 21-41 are pending as of the response filed on 11/22/22. Claims 1-20 have been previously canceled.

The nonstatutory double patenting rejections over copending claims 17301820; US 9765028; US 9415041; US 9226896; US 8541451; US 8921396; US 11008289; US 10550081; and US 10100013 are withdrawn in consideration of the acceptance of the terminal disclaimer filed on 11/22/22.

The provisional statutory double patenting rejection over claims 21-27 and 32-41 over claims 30-36, 44-47, and 51-56 of copending appl. 17301820 is withdrawn in view of the amendments filed in the copending application.

A new provisional statutory double patenting rejection over newly added claims of 17301820 is made; as this new rejection is not based on amendments made in this application, and is instead based on amendments made in the copending application, this action is non-final.

2. Claims 21-41 were examined. Claims 32, 34, and 36 are rejected. Claims 21-31 are allowed. Claims 33, 35, and 37-41 are objected to.

Claim Rejections-Statutory Double Patenting

3. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process... may obtain a patent therefor..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the claims that are directed to the same invention so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 32, 34, and 36 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 62-64 of copending Application No. 17301820 (reference application). Claims 32, 34, and 36 are shown below with the corresponding claims 62-64 of the copending application.

32. (Previously Presented) A pharmaceutical composition comprising: a crystalline freebase of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1-ylmethyl)benzoyl]methylamino}-ethyl)piperidin-4-yl ester that is dissolved in a solvent; wherein the crystalline freebase is characterized by a powder x-ray diffraction pattern comprising diffraction peaks at 2θ values of 6.6±0.1, 13.1±0.1, 18.6±0.1, 19.7±0.1, and 20.2±0.1.

62. (New) A pharmaceutical composition comprising: a crystalline freebase of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1-ylmethyl)benzoyl]methylamino}-ethyl)piperidin-4-yl ester in a solution; wherein the crystalline freebase is characterized by a powder x-ray diffraction pattern comprising diffraction peaks at 2θ values of 6.6±0.1, 13.1±0.1, 18.6±0.1, 19.7±0.1, and 20.2±0.1.

These claims are identical in scope, as both sets of claims are drawn to a pharmaceutical composition comprising the same crystalline form of the same compound in solution, i.e., dissolved in a solvent.

34. (Previously Presented) A pharmaceutical composition comprising a pharmaceutically acceptable carrier and a crystalline freebase of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1-ylmethyl)benzoyl]methylamino}ethyl)piperidin-4-yl ester characterized by a powder x-ray diffraction comprising diffraction peaks at 2θ values of 6.6±0.1, 13.1±0.1, 18.6±0.1, 19.7±0.1, and 20.2±0.1, and further characterized by having five or more additional diffraction peaks at 2θ values selected from 8.8±0.1, 10.1±0.1, 11.4±0.1, 11.6±0.1, 14.8±0.1, 15.2±0.1, 16.1±0.1, 16.4±0.1, 16.9±0.1, 17.5±0.1, 18.2±0.1, 19.3±0.1, 19.9±0.1, 20.8±0.1, 21.1±0.1, 21.7±0.1, and 22.3±0.1, wherein the crystalline freebase is dissolved in the pharmaceutically acceptable carrier.

63. (New) A pharmaceutical composition comprising a pharmaceutically acceptable carrier and a crystalline freebase of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1-ylmethyl)benzoyl]methylamino}-ethyl)piperidin-4-yl ester characterized by a powder x-ray diffraction pattern comprising diffraction peaks at 2θ values of 6.6±0.1, 13.1±0.1, 18.6±0.1, 19.7±0.1, and 20.2±0.1, and further characterized by having five or more additional diffraction peaks at 2θ values selected from 8.8±0.1, 10.1±0.1, 11.4±0.1, 11.6±0.1, 14.8±0.1, 15.2±0.1, 16.1±0.1, 16.4±0.1, 16.9±0.1, 17.5±0.1, 18.2±0.1, 19.3±0.1, 19.9±0.1, 20.8±0.1, 21.1±0.1, 21.7±0.1, and 22.3±0.1, wherein the crystalline freebase is in solution with the pharmaceutically acceptable carrier.

These claims are identical in scope, as both sets of claims are drawn to a pharmaceutical composition comprising a pharmaceutically acceptable carrier and the same crystalline form of the same compound dissolved in a pharmaceutically acceptable carrier, i.e., in solution with a pharmaceutically acceptable carrier.

36. (Previously Presented) A pharmaceutical composition comprising a solution of a crystalline freebase of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1-ylmethyl)benzoyl]methylamino}-ethyl)piperidin-4-yl ester characterized by (i) a powder x-ray diffraction comprising diffraction peaks at 2θ values of 6.6±0.1, 13.1±0.1, 18.6±0.1, 19.7±0.1, and 20.2±0.1 or (ii) a melting point of about 125° C, dissolved in a carrier.

64. (New) A pharmaceutical composition comprising a solution of a crystalline freebase of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1-ylmethyl)benzoyl]methylamino}-ethyl)piperidin-4-yl ester characterized by (i) a powder x-ray diffraction pattern comprising diffraction peaks at 2θ values of 6.6±0.1, 13.1±0.1, 18.6±0.1, 19.7±0.1, and 20.2±0.1 or (ii) a melting point of about 125°C.

These claims are identical in scope, as both sets of claims are drawn to a pharmaceutical composition comprising a solution of the same crystalline form of the same compound, i.e., dissolved in a carrier.

This is a provisional statutory double patenting rejection since the claims directed to the same invention have not in fact been patented.

Claim Objection

4. Claims 33, 35, and 37-41 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Information Disclosure Statement

5. The IDS filed on 11/22/22 has been considered.

Conclusion

6. Claims 32, 34, and 36 are rejected. Claims 21-31 are allowed. Claims 33, 35, and 37-41 are objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARAH PIHONAK whose telephone number is (571)270-7710. The examiner can normally be reached Monday-Friday 9:00-5:30 EST.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kortney Klinkel can be reached on 571-270-5239. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO

Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SARAH . PIHONAK
Primary Examiner
Art Unit 1627

/SARAH PIHONAK/
Primary Examiner, Art Unit 1627

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Theravance Biopharma R&D IP, LLC

Application No.: 17/841,567 Confirmation No.: 4866

Filed: June 15, 2022 Art Unit: 1627

For: CRYSTALLINE FREEBASE FORMS OF BIPHENYL COMPOUND Examiner: PIHONAK, SARAH

AMENDMENT AND REPLY UNDER 37 C.F.R. §1.111

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Commissioner:

This Amendment and Reply is responsive to the Non-Final Office Action dated December 28, 2022, in the above-identified patent application. The Office Action set a three-month period for response, and therefore, this reply is timely filed before its due date of March 28, 2023. In response to the Office Action, entry of the following amendments and consideration of the following remarks is respectfully requested.

Amendments to the Claims are reflected in the listing of claims which begin on page 2 of this paper.

Remarks/Arguments begin on page 4 of this paper.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1-20. (Canceled)

21. (Previously Presented) A process for preparing a pharmaceutical composition, the process comprising:

dissolving a crystalline freebase of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1-ylmethyl)benzoyl]methylamino}-ethyl)piperidin-4-yl ester in a solvent to form a solution; wherein the crystalline freebase is characterized by a powder x-ray diffraction pattern comprising diffraction peaks at 2θ values of 6.6±0.1, 13.1±0.1, 18.6±0.1, 19.7±0.1, and 20.2±0.1.

22. (Previously Presented) The process of claim 21, further comprising combining the solution with an aqueous pharmaceutical carrier.

23. (Previously Presented) The process of claim 21, wherein the solvent is an aqueous pharmaceutical carrier.

24. (Previously Presented) The process of claim 21, wherein the crystalline freebase is further characterized by five or more additional diffraction peaks at 2θ values selected from 8.8±0.1, 10.1±0.1, 11.4±0.1, 11.6±0.1, 14.8±0.1, 15.2±0.1, 16.1±0.1, 16.4±0.1, 16.9±0.1, 17.5±0.1, 18.2±0.1, 19.3±0.1, 19.9±0.1, 20.8±0.1, 21.1±0.1, 21.7±0.1, and 22.3±0.1.

25. (Previously Presented) The process of claim 21, wherein the crystalline freebase is further characterized by a powder x-ray diffraction pattern having peak positions in accordance with the peak positions shown in FIG. 1.

26. (Previously Presented) The process of claim 21, wherein the crystalline freebase is further characterized by a melting point of about 125° C.

27. (Previously Presented) The process of claim 21, wherein the crystalline freebase is further characterized by a differential scanning calorimetry thermogram in accordance with that shown in FIG. 4.

28. (Previously Presented) The process of claim 21, wherein the pharmaceutical composition is isotonic.

29. (Previously Presented) The process of claim 21, wherein the pharmaceutical composition has a pH of about 4-6.

30. (Previously Presented) The process of claim 21, wherein the pharmaceutical composition is buffered with citrate buffer to a pH of about 5.

31. (Previously Presented) The process of claim 21, wherein the pharmaceutical composition contains about 0.05 μg/mL to about 10 mg/mL of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1-ylmethyl)benzoyl]methylamino}-ethyl)piperidin-4-yl ester.

32.-41. (Canceled)

REMARKS

Applicant respectfully requests reconsideration of this application in view of the above amendments and following remarks.

Amendments to the Claims

By this paper, claims 32-41 are canceled without prejudice or disclaimer. No new matter is added by virtue of this amendment; thus, entry thereof is respectfully requested. Applicant reserves the right to pursue canceled subject matter in a continuing application.

Rejections under 35 U.S.C. §101

Claims 32, 34, and 36 are provisionally rejected under 35 U.S.C. §101 as claiming the same invention as that of claims 62-64 of co-pending U.S. Application No. 17/301,820.

Without acquiescing to the propriety of the rejection, and in a sincere attempt to expedite prosecution, Applicant has canceled claims 32, 34, and 36, and thus respectfully requests that the rejection be withdrawn.

Claim Objections

Claims 33, 35, and 37-41 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all the limitations of the base claim and any intervening claims.

Without acquiescing to the propriety of the rejection, and in a sincere attempt to expedite prosecution, Applicant has canceled claims 33, 35, and 37-41, and thus respectfully requests that the objections be withdrawn.

Allowed Subject Matter

Applicant thanks the Office for acknowledging the patentability of claims 21-31.

CONCLUSION

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-4561. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extension fees to Deposit Account No. 50-4561.

Respectfully submitted,

Dated: March 23, 2023

By /Joy Lynn Nemirow/
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NOTICE OF ALLOWANCE AND FEE(S) DUE

183577 7590 04/05/2023

Sheppard Mullin Richter & Hampton LLP/Theravance
650 Town Center Drive, 10th Floor
Costa Mesa, CA 92626

EXAMINER
PIHONAK, SARAH

ART UNIT	PAPER NUMBER
1627	

DATE MAILED: 04/05/2023

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/841,567	06/15/2022	Grahame WOOLLAM	71TD-343862-US10	4866

TITLE OF INVENTION: CRYSTALLINE FREEBASE FORMS OF A BIPHENYL COMPOUND

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1200	$0.00	$0.00	$1200	07/05/2023

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 40% the amount of undiscounted fees, and micro entity fees are 20% the amount of undiscounted fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications. **Because electronic patent issuance may occur shortly after issue fee payment, any desired continuing application should preferably be filed prior to payment of this issue fee in order not to jeopardize copendency.**

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

183577 7590 04/05/2023
Sheppard Mullin Richter & Hampton LLP/Theravance
650 Town Center Drive, 10th Floor
Costa Mesa, CA 92626

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/841,567	06/15/2022	Grahame WOOLLAM	71TD-343862-US10	4866

TITLE OF INVENTION: CRYSTALLINE FREEBASE FORMS OF A BIPHENYL COMPOUND

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1200	$0.00	$0.00	$1200	07/05/2023

EXAMINER	ART UNIT	CLASS-SUBCLASS
PIHONAK, SARAH	1627	514-316000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/AIA/122 or PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. Fees submitted: ❑ Issue Fee ❑ Publication Fee (if required)

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

❑ Electronic Payment via Patent Center or EFS-Web ❑ Enclosed check ❑ Non-electronic payment by credit card (Attach form PTO-2038)

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. **Change in Entity Status** (from status indicated above)

❑ Applicant certifying micro entity status. See 37 CFR 1.29

❑ Applicant asserting small entity status. See 37 CFR 1.27

❑ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/841,567	06/15/2022	Grahame WOOLLAM	71TD-343862-US10	4866

183577 7590 04/05/2023

Sheppard Mullin Richter & Hampton LLP/Theravance
650 Town Center Drive, 10th Floor
Costa Mesa, CA 92626

EXAMINER	
PIHONAK, SARAH	
ART UNIT	PAPER NUMBER
1627	

DATE MAILED: 04/05/2023

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 17/841,567	Applicant(s) WOOLLAM, Grahame	
	Examiner SARAH PIHONAK	Art Unit 1627	AIA (FITF) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☑ This communication is responsive to 3/23/23.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☑ The allowed claim(s) is/are 21-31 . As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see **http://www.uspto.gov/patents/init_events/pph/index.jsp** or send an inquiry to **PPHfeedback@uspto.gov.**

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some* c) ☐ None of the:

   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____ .

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____ .

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☑ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date. _____.
5. ☐ Examiner's Amendment/Comment
6. ☑ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/SARAH PIHONAK/
Primary Examiner, Art Unit 1627

Notice of Pre-AIA or AIA Status

The present application is being examined under the pre-AIA first to invent provisions.

Status of Claims

1. Claims 21-31 are pending as of the response and amendments filed on 3/23/23. Claims 1-20 and 32-41 have been canceled.

The provisional statutory double patenting rejection of claims 32, 34, and 36 over the claims of 17301280 is withdrawn as these claims have been canceled.

2. Claims 21-31 are allowed.

Reasons for Allowance

3. The following is an examiner's statement of reasons for allowance: crystalline freebase form of biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1-ylmethyl)benzoyl]methylamino}ethyl)piperidin-4-yl ester having a powder X-ray diffraction pattern comprising diffraction peaks at 2θ values of 6.6±0.1, 13.1±0.1, 18.6±0.1, 19.7±0.1, and 20.2±0.1, in accordance with that shown in Fig. 1 (form III as defined in Applicant's specification), is not taught or suggested by the closest prior art, Axt, WO 2006099165, and Mammen, US 20050203133 (both cited in an IDS). Axt teaches crystalline polymorphs I and II of freebase biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1-ylmethyl)benzoyl]methylamino}ethyl)piperidin-4-yl ester; however, these polymorphs are prepared by different processes using different solvents from the instantly claimed crystalline polymorph, are characterized by different PXRD patterns, and the polymorphs of Axt have

melting peaks at about 102.7 °C and 98.6 °C. Mammen teaches crystalline freebase biphenyl-2-ylcarbamic acid 1-(2-{[4-(4-carbamoylpiperidin-1-ylmethyl)benzoyl]methylamino}ethyl)piperidin-4-yl ester, however, this crystalline form is taught to be prepared by a different process compared to the crystalline form of the instant claims, using different solvents (Mammen teaches a combination of H_2O:acetonitrile at a 1:1 ratio or a combination of acetonitrile: MTBE at a 1:2 ratio, while the instantly claimed form is prepared using only acetonitrile, toluene, or a combination of isopropyl acetate:water). Mammen also does not teach or suggest the crystalline form having a powder X-ray diffraction pattern comprising diffraction peaks at 2θ values of 6.6±0.1, 13.1±0.1, 18.6±0.1, 19.7±0.1, and 20.2±0.1.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Information Disclosure Statement

4. The IDS filed on 3/23/23 has been considered.

Conclusion

5. Claims 21-31 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARAH PIHONAK whose telephone number is (571)270-7710. The examiner can normally be reached Monday-Friday 9:00-5:30 EST.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kortney Klinkel can be reached on 571-270-5239. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SARAH . PIHONAK
Primary Examiner
Art Unit 1627

/SARAH PIHONAK/
Primary Examiner, Art Unit 1627